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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,264	01/20/2006	Martin F. Bachmann	17000660000	5243
26111 7590 10/18/2007 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			EXAMINER OGUNBIYI, OLUWATOSIN A	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 10/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,264	Applicant(s) BACHMANN ET AL.	
	Examiner Oluwatosin Ogunbiyi	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-15, 17 and 23-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

The amendments to the claims filed 1/20/2006 have been entered into the record. Claims 16 and 18-22 have been cancelled. Claims 23-26 have been added. Claims 1-15, 17 and 23-26 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Group I: claims 1-5, 6-10, 11-14, 23, 24 and 25, drawn to a composition for enhancing the production of IFN alpha in an animal comprising:
 - (a) a liposome;
 - (b) at least one A-type CpG;wherein all nucleotides of the A-type CpG oligonucleotide (b) are phosphodiester nucleotides, and further wherein said A-type CpG (b) is bound to said liposome (a).
- II. Group II: claims 15, 17 and 26 drawn a method for enhancing the production of IFN alpha in an animal, said method comprising introducing into said animal the composition of claim 1.

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The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- I. The technical feature of Group I is the composition for enhancing the comprising:
 - (a) a liposome;
 - (b) at least one A-type CpG;wherein all nucleotides of the A-type CpG oligonucleotide (b) are phosphodiester nucleotides, and further wherein said A-type CpG (b) is bound to said liposome (a). This technical feature is anticipated by. Klinman et al. US 2003/060440 A1 March 27, 2003. See paragraphs 13,105, 113,116, 138. See especially paragraph 113 and 138. Klinman et al teaches D type (Also known as A-type See specification p. 2 line 22-24) CpG oligonucleotide covalently bound to a liposome (paragraph 138) wherein all the nucleotides of the D type/A type oligonucleotide are phosphodiester (parargraph 113).
- II. The technical feature of Group II is a method for enhancing the production of IFN alpha in an animal, said method comprising introducing into said animal the composition of claim 1.

Group I lacks unity with Group II because the technical feature of Group I is anticipated by the art and therefore not "special" within the meaning of PCT Rule 13.2 because it does not provide for a contribution that the claimed invention makes over the art.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so

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linked as to form a single general inventive concept under PCT Rule 13.1. The species are as follows:

Group I

- I. Species of A-type oligonucleotide – recombinant oligonucleotide; a genomic oligonucleotide; a synthetic oligonucleotide; a plasmid-derived oligonucleotide; a PCR product; a single-stranded oligonucleotide; and a double-stranded oligonucleotide.
- II. Species of liposome - neutral, anionic, cationic, stealth, cationic stealth

The following claims are generic and deemed to correspond to the species listed above in the following manner: claims 1-6, 8-12, 14, 15, 23-25.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

- I. The technical feature linking the species of A-type CpG is not novel and is not defined over the prior art. Paragraph 136 of Klinman et al cited above discloses synthetic A-type CpG (also known as D-type CpG).
- II. The technical feature linking the species of liposome is not novel and is not defined over the prior art. Kasid et al (US 6,333,314 B1. Dec. 25, 2001) discloses the species of cationic liposome (see abstract).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

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all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

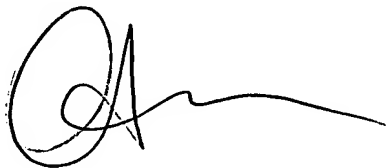
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 7am-4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Oluwatosin Ogunbiyi

Patent Examiner

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PATRICIA A. DUFFY
PRIMARY EXAMINER